UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. VULTO CREAMERY LLC, a limited liability company, and JOHANNES H. VULTO, an individual, Defendants.	)	Civil No. 3:18 cv 00331 (BKS/DEP)

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Vulto Creamery LLC ("Vulto Creamery"), a limited liability company, and Johannes H. Vulto, an individual (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint, having appeared and consented to entry of this Consent Decree for Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action under 21 U.S.C. § 332 and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are:

A. adulterated within the meaning of 21 U.S.C. § 342(a)(1), in that they bear or contain a poisonous and deleterious substance, *Listeria monocytogenes* ("*L. mono*"), which renders them injurious to health; and

B. adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth and rendered injurious to health.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by doing or causing to be done any act that causes the adulteration, within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4), of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. Upon entry of this Decree, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), who receive actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly

receiving, manufacturing, preparing, processing, holding, labeling, packing, or distributing any articles of food, at or from their facility located at 44 West Street, Walton, New York 13856-1479, or at any other location(s) at or from which Defendants now or in the future directly or indirectly receive, manufacture, prepare, process, hold, label, pack, or distribute any articles of food ("facility"), unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants and/or their families, which is qualified to collect product and environmental samples from within the facility and analyze those samples for the presence of *Listeria*, including *L. mono*, using a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the *Listeria* Monitoring Program discussed in paragraph 5(C) below;

B. Defendants retain, at their expense, an independent expert(s) (the "sanitation expert") having no personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants' facility and to determine whether the equipment, methods, processes, and controls are operated and administered in conformity with this Decree, the Act, and its implementing regulations. The expert's qualifications shall include, but not be limited to, developing procedures to adequately control for the risk of *L. mono*. Defendants shall

notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants' sanitation expert, in consultation with the laboratory, after reviewing all FDA observations from March 2017 to the present, develops a written *Listeria* Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written sanitation control program that establishes adequate methods, processes, and controls for receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing articles of food to minimize the risk of introduction of pathogenic *Listeria*, any other poisonous or deleterious substances, and filth, into Defendants' food products, and to ensure that Defendants' foods are not adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4). Such methods, processes, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facility and all equipment therein suitable for use in receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") to ensure that the facility and equipment therein are continuously maintained in a sanitary condition;

(2) A written employee training program that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training. Defendants' sanitation expert shall test to ensure that each employee fully understands the substance of the employee training program;

(3) An effective program of environmental monitoring and testing of the facility conducted by the laboratory, to ensure that *Listeria species* ("*Listeria spp.*") are

controlled, and that *L. mono* is not present within the facility. Environmental monitoring shall include, but not be limited to, (a) collecting swab samples from food-contact and non-food-contact surfaces, equipment, and other environmental sites throughout the facility where the raw ingredients, in-process, and finished articles of foods are received, manufactured, prepared, processed, packed, labeled, held, and/or distributed, and common areas that could be reservoirs for cross-contamination, and (b) analyzing collected samples, in a manner acceptable to FDA. Defendants' environmental monitoring program shall include, but not be limited to, specifications concerning the quantity of swabs, location of swabs, and frequency of swabbing. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) business days of receipt by Defendants; and

(4) A written plan for remedial action should *Listeria spp.*, *L. mono*, or any other organism be detected;

D. Defendants assign continuing responsibility for the operation of the *Listeria* Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

E. FDA approves, in writing, the *Listeria* Monitoring Program discussed in paragraph 5(C) prior to implementation;

F. Defendants make written copies of the *Listeria* Monitoring Program available and accessible to all of their employees;

G. The sanitation expert conducts a comprehensive inspection of the facility, its equipment, the methods and controls used to receive, manufacture, prepare, process, hold,

label, pack, and distribute foods to determine whether Defendants have effectively implemented the *Listeria* Monitoring Program, have adequately addressed all FDA observations documented in March 2017 and any other violations identified subsequently, and are operating in compliance with this Decree, the Act, and its implementing regulations. At a minimum, the comprehensive inspection shall include environmental swabbing of Defendants' facility for *Listeria spp.*, identifying and eliminating harborage sites for *L. mono*, and conducting a root cause analysis of any *L. mono* contamination. The expert shall submit all findings to Defendants and FDA concurrently within ten (10) business days after completion of the inspection;

H. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including:

(1) Producing documentation that Defendants have cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing articles of food, and documentation that Defendants have received laboratory confirmation from environmental swabbing that *L. mono* is no longer present in the facility;

(2) Identifying specific measures that Defendants have taken to address each of the violations documented by FDA in March 2017 and any subsequent violations; and

(3) Providing a copy of the *Listeria* Monitoring Program;

I. Within twenty (20) business days after entry of this Decree, Defendants shall, pursuant to a written destruction plan approved in writing by FDA, destroy under FDA's

supervision all raw ingredients and all in-process and finished articles of food currently in their custody, control, or possession;

J. Defendants recall, to the retail level, and destroy all cheese distributed since April 5, 2017;

K. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of the facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

L. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 5(A) through (J) of this Decree, the Act, and its implementing regulations; and

M. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs 5(A) through (K), including the travel incurred by specialized investigatory and expert personnel, at the rates set forth in paragraph 11 below.

6. Upon entry of the Decree, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree pursuant to paragraph 17 below, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4) while such articles are held for sale after shipment of one or more components in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this Decree.

7. Immediately upon resuming operations after completing the requirements of paragraph 5 and receiving notice from FDA pursuant to paragraph 5(L), Defendants shall, in consultation with the laboratory and the sanitation expert, continuously and effectively implement the following steps to prevent future contamination from *L. mono*, other pathogenic organisms, and/or filth in their food products and facility. Defendants shall:

A. Effectively implement, on an ongoing basis, the *Listeria* Monitoring Program developed pursuant to paragraph 5(C). In the event that Defendants, their sanitation expert, or laboratory determines that the *Listeria* Monitoring Program needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20) days prior their expected implementation, and such changes shall not be implemented prior to FDA approval in writing;

B. Conduct environmental monitoring and testing to ensure that the SSOPs continue to control the *L. mono* hazard and are consistently being followed. Environmental monitoring shall include, but not be limited to (i) collecting swab samples from food-contact and non-food-contact surfaces, equipment, other environmental sites throughout Defendants' facility

where articles of food are received, manufactured, prepared, processed, packed, held, labeled, and/or distributed, up to and including final packaging, and common areas that could be reservoirs for cross-contamination, and (ii) analyzing such samples for the presence of *Listeria spp.* Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing for approval by FDA in writing before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants. Defendants' environmental testing must include, at a minimum, all of the following:

(1) If a food- or non-food-contact surface tests positive for *Listeria spp.* during routine testing, intensified sampling must be conducted as soon as possible, in conjunction with intensified sanitation measures. The details of the intensified sampling and sanitation measures should be addressed in the remedial action component of the *Listeria* Monitoring Program; and

(2) Any *Listeria spp.* isolate from a food-contact surface must be tested further to determine if it is *L. mono*. In addition, all food products that have come in contact with a site that tests positive for the general strain *Listeria spp.* must be placed on hold pending laboratory test results of those food products and further testing of the *Listeria spp.* isolate from the food-contact surface. Defendants shall submit the sampling scheme for food product testing to FDA, which sampling scheme must be acceptable to FDA. The food products can be released only if laboratory test results for the food products are negative for *L. mono* and the *Listeria spp.* isolate from the food-contact surface is not *L. mono*; if the laboratory test results for the food products and/or *Listeria spp.* isolate from food-contact surface are positive for *L. mono*, all food products manufactured from the time the laboratory sample(s) testing positive for

L. mono was collected must be destroyed at Defendants' expense, under FDA's supervision, and according to a written destruction plan submitted by Defendants and approved in writing by FDA prior to implementation; and

C. Conduct finished product testing in the following manner:

(1) Defendants shall test all lots of cheese for *L. mono* for at least five consecutive production days using a testing method approved in writing in advance by FDA;

(2) After the completion of testing under paragraph 7(C)(1), Defendants shall test at least one lot of each cheese per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 7(C)(2), Defendants shall test at least one lot of each cheese every five (5) production days for the next three (3) months;

(4) After the completion of testing under paragraph 7(C)(3), Defendants shall test at least one lot of each cheese monthly thereafter; and

(5) If any cheese tested pursuant to paragraphs 7(C)(1)-(4) is positive for *L. mono* (collectively, "positive food samples"), then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA, all positive food samples, as well as all food manufactured since the positive food samples were collected. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations. After correcting the cause of the

contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

8. If Defendants terminate or modify in any way their service contract with the laboratory retained pursuant to paragraph 5(A), Defendants shall notify FDA within five (5) business days after such termination or modification. In this event, Defendants shall provide a copy of the new or modified service contract to FDA within five (5) business days after such service contract is executed.

9. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the facility and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, labeling, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, labeling, and packaging material; and to examine and copy all records related to receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business, including reorganization,

relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) business days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) business days after providing a copy of this Decree to a prospective successor or assign.

11. Defendants shall reimburse the government for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including the travel incurred by specialized investigatory and expert personnel. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $93.26 per hour and fraction thereof per representative for inspection or investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

12. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its

implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing any articles of food;

B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with microorganisms or filth; and/or

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 11 of this Decree.

13. Upon receipt of an FDA order described in paragraph 12, Defendants shall immediately and fully comply with the terms of the order, and shall continue to comply with such terms, until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

14. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of one thousand five hundred dollars ($1,500.00) for each day that Defendants fail to comply with this Decree; an additional sum of seven hundred fifty dollars ($750.00) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

15. If any Defendant violates this Decree and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

16. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

17. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of this Decree by personal service or certified mail (restricted delivery, return receipt

requested), to each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within twenty (20) business days after the date of entry of this Decree an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

18. Defendants shall immediately and prominently post a copy of this Decree in an employee common area at the facility and shall ensure that the Decree remains continuously posted.

19. Defendants shall, within ten (10) business days after entry of this Decree, hold a general meeting or series of smaller meetings for employees of the facility, at which they shall describe the terms and obligations of this Decree, and shall hold a similar meeting with each new employee of the facility within five (5) business days of the start of employment.

20. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, heirs, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) business days after each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names and positions of all persons who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days after receiving a

request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Defendants shall address all communications with FDA required under this Decree to Program Division Director, Office of Human and Animal Feeds Operations Division 1 East, Food and Drug Administration, 158-15 Liberty Ave., Jamaica, New York 11433, and shall reference this civil action by case name and civil action number in such communications.

22. This Decree resolves only those claims set forth in the Complaint. Defendants acknowledge and agree that entry of this Decree does not preclude the United States from bringing additional civil and administrative claims or criminal charges against Defendants that relate to or involve FDA-regulated products, whether or not arising out of the conduct alleged in the Complaint.

23. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 30th day of March, 2018.

Brenda K. Sannes
U.S. District Judge

Entry consented to:

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Individually

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